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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K073621**

Applicant information:

Date Prepared:	December 21, 2007
Name: Address	Art Optical Contact Lens, Inc. 3175 3 Mile Road NW Walker, Michigan 49534
Contact Person: Phone number:	Mike Johnson, FCLSA Director of Consultation Services (616) 559-5167
Consultant: Phone number	Med-Vice Consulting, Inc. Martin Dalsing (970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**IntelliWave1, Soft Daily Wear Contact Lens (Acofilcon B)** **IntelliWave2, Soft Daily Wear Contact Lens (Hioxifilcon B)**

Equivalent Devices:

The **IntelliWave1,** Soft Daily Wear Contact Lenses (Acofilcon B) and **IntelliWave2,** Soft Daily Wear Contact Lenses (Hioxifilcon B) are substantially equivalent to the following predicate devices in terms of contact lens material, intended use and design.

Predicate devices include:

Contaflex GM3 49% manufactured by Contamac Ltd; K024045

BENZ-G 3X manufactured by Benz Research and Development, K964528

IntelliWave1 Device Description:

The **IntelliWave1,** Soft Daily Wear Contact Lenses are fabricated from (Acofilcon B), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, (acofilcon B) is a terpolymer based on high purity Glycerol Methacrylate 2,3-Dihydroxypropyl Methacrylate (GMA), with N-vinyl-2-pyrrolidone (NVP), methyl methacrylate (MMA), and 2-hydroxyethyl methacrylate (2-HEMA) and cross-linked with Diallyl Maleate (DAM). It consists of 51% acofilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium tetraborate. The lens material is available in clear and with a blue visibility-handling tint, Color additive 'Reactive Blue 4' 21 CFR part 73.2121.

The Physical properties of the lens are:

Refractive Index	1.52 (dry) 1.42 (hydrated)
Light Transmission	greater than 94%
Surface Character	hydrophilic
Water Content	49 %
Specific Gravity	1.142 (hydrated)
Oxygen Permeability	15.89 X 10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

IntelliWave1 Indications for Use

The **IntelliWave1,** Sphere (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave1,** Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters.

The **IntelliWave1,** Multifocal (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave1,** Multifocal Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

IntelliWave2 Device Description:

The **IntelliWave2,** Soft Daily Wear Contact Lenses are fabricated from (Hioxifilcon B), which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The non-ionic lens material, hioxifilcon B is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 51% hioxifilcon B and 49% water by weight when immersed in normal saline solution buffered with sodium tetraborate. The lens material is available clear and with a blue visibility handling tint, phthalocyanato (2) - (copper).

The Physical properties of the lens are:

Refractive Index	1.51 (dry) 1.42 (hydrated)
Light Transmission	greater than 94%
Surface Character	hydrophilic
Water Content	49 %
Specific Gravity	1.137 (hydrated)
Oxygen Permeability	16.40 X 10^{-11} (cm^2/sec) (ml O_2/ml x hPa @ 35°C), (revised Fatt method).

IntelliWave2 Indications for Use

The **IntelliWave2,** Sphere (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave2,** Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters.

The **IntelliWave2,** Multifocal (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave2,** Multifocal Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The established safety profile (pre-clinical toxicology, clinical study data, manufacturing/chemistry data) of the device is equivalent to the Contaflex GM3 49% and the BENZ-G 3X. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates the production method, lens function and material characteristics of the **IntelliWave1,** Soft Daily Wear Contact Lens (Acofilcon B) and **IntelliWave2**, Soft Daily Wear Contact Lens (Hioxifilcon B), as well as the predicate devices.

Substantial Equivalence Matrix

	IntelliWave new device	**CONTAFLEX GM3 49% (acofilcon B) predicate device**	**BENZ-G3X (hioxifilcon B) predicate device**
Intended Use	same as predicate device	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	same as predicate device	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	same as predicate device	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Production Method	same as predicate device	Lathe-cut	Lathe-cut
FDA Group #	same as predicate device	Group # 1 < 50% Water, Nonionic Polymers	Group # 1 < 50% Water, Nonionic Polymers
USAN name	same as predicate device	Acofilcon B	Hioxifilcon B
Water Content	same as predicate device	48.0%	48.0%
Oxygen Permeability	same as predicate device	15.89 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	16.40 X 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	same as predicate device	1.142	1.137

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2008

Art Optical Contact Lens, Inc.
c/o Mr. Martin Dalsing
Medvice Consulting, Inc
806 Kimball Ave.
Grand Junction, CO 81501

Re: K073621
Trade/Device Name: IntelliWave1 Soft Daily Wear Contact Lens (acofilcon B), clear and blue visibility tint
IntelliWave2 Soft Daily Wear Contact Lens (hioxifilcon B), clear and blue visibility tint
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 25, 2008
Received: June 26, 2008

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **IntelliWave1, Soft Daily Wear Contact Lens (Acofilcon B) clear and blue visibility tint.**

INDICATIONS FOR USE:

The **IntelliWave1,** Sphere (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave1,** Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters.

The **IntelliWave1,** Multifocal (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave1,** Multifocal Toric (Acofilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

Mya Smith
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
(Optional Format 1-2-96)

or Over-The-Counter Use ___

510(k) Number K073621

INDICATIONS FOR USE STATEMENT

Device Name: IntelliWave2, Soft Daily Wear Contact Lens (Hioxifilcon B) clear and blue visibility tint.

INDICATIONS FOR USE:

The **IntelliWave2,** Sphere (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **IntelliWave2,** Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters.

The **IntelliWave2,** Multifocal (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity and are presbyopic requiring add power of up to +4.00 diopters.

The **IntelliWave2,** Multifocal Toric (Hioxifilcon B) Soft Contact Lenses for daily wear are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with nondiseased eyes and/or possesses refractive astigmatism not exceeding 5.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

(Optional Format 1-2-96)

510(k) Number K073621